

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Ni et al.

Docket No.: PF293D2

Patent No.: 7,495,084

Issued: February 24, 2009

For: Antibodies to T1 Receptor-Like Ligand II

**APPLICATION FOR PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(d)**

MS Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentees hereby request reconsideration of the Patent Term Adjustment (PTA) indicated on the face of U.S. Patent No. 7,495,084. Patentees believe the correct PTA is 1168 days (not 611 days) under the interpretation of 35 U.S.C. § 154 articulated by the U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, No. 07-1492 (September 30, 2008) ("*Wyeth*") (attached as Exhibit A herewith).

This request is being timely made, as it is submitted within two months of the issuance of the patent, and could not have been made in an application for PTA under 37 C.F.R. § 1.705(b) because the request pertains to the issue date of the captioned patent and the appropriate PTA due under 35 U.S.C. § 154(b)(1)(B). The requirements of 37 C.F.R. § 1.705(b)(1) are satisfied by the electronic fee transmittal submitted herewith, authorizing payment of the fee set forth in 37 C.F.R. 1.18(e). The requirements of 37 C.F.R. § 1.705(b)(2) are satisfied by the following Statement of Facts.

STATEMENT OF FACTS

1. The application for the instant patent was filed on October 27, 2003, and is thus eligible for PTA under 35 U.S.C. § 154.
2. The instant application is not subject to a terminal disclaimer.

3. The instant application was filed on October 27, 2003. However, the Office failed to initially act on the application within the 14 month permitted time frame allowed under 35 U.S.C. § 154(b)(1)(A). In particular, a restriction requirement was not mailed until July 7, 2006. Thus, Patentees are entitled to a PTA of 557 days due to the Patent Office's delay from the day after the date fourteen months after the application was filed (December 28, 2004) to the date of mailing of the first notification under 35 U.S.C. 132 (July 7, 2006). *See* 35 U.S.C. § 154(b)(1)(A) and 37 C.F.R. §§ 1.702(a)(1) & 1.703(a)(1).

4. An office action was mailed on May 22, 2007.

5. A response to the office action was filed on November 23, 2007 with a petition for an extension of time of three months. Pursuant to 37 C.F.R. § 1.704, this filing incurred a PTA reduction of 93 days from the day after the date three months after the mailing of the office action (August 23, 2007) to the date of the response (November 23, 2007).

6. A notice of informal or non-responsive amendment was mailed on April 8, 2008.

7. A response to this notice was filed on April 18, 2008. Pursuant to 37 C.F.R. § 1.704(c)(7), this filing incurred a PTA reduction of 147 days from the day after the date the prior response was filed (November 24, 2007) to the date of the response to this notice (April 18, 2008).

8. On August 7, 2008, a notice of allowance was mailed. Together with the notice of allowance, a Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) was mailed indicating a PTA of 317 days, taking the above adjustments and reductions into account.

9. The issue fee transmittal form was filed, and the issue fee was timely paid, on September 9, 2008.

10. The instant patent was issued on February 24, 2009. Accordingly, the Office failed to issue the patent within four months of payment of the issue fee. Patentees are entitled to a PTA of 46 days due to the Patent Office's delay from the day after the date

four months after the issue fee was paid and all outstanding requirements were satisfied (September 10, 2008) to the date issuance (February 24, 2009). *See* 37 C.F.R. §§ 1.702(a)(4) & 1.703(a)(6).

11. The Office also failed to issue the patent within three years pursuant to 35 U.S.C. § 154(b)(1)(B). Thus, Patentees are entitled to PTA due to the Patent Office's delay of 851 days from the day after the date three years after the application was filed (October 28, 2006) to the date that the patent was issued (February 24, 2009), to the extent that such delay does not overlap with other periods of delay. *See* 35 U.S.C. §§ 154(b)(1)(B) and 154(b)(2) and 37 C.F.R. § 1.703(b). As explained further below, this delay overlaps with the 46 days of delay due to failure to issue the patent within four months of paying the issue fee in ¶ 10 but not with the 557 days of delay in ¶ 3 for failure to act within 14 months of filing of the application. Thus, the Patentees are entitled to a PTA of 805 days (not 248 days as determined by the Office) due to the 851 days of delay for not issuing the patent within three years of filing minus the 46 days of overlap with the delay in ¶ 10 for failing to issue the patent within four months of payment of the issue fee.

12. Other than the circumstances described above, there have been no circumstances that could reasonably be construed as a failure to engage in reasonable efforts to conclude processing or examination of this application.

13. On September 30, 2008, the U.S. District Court for the District of Columbia decided *Wyeth v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008) ("*Wyeth*") (attached as Exhibit A). In *Wyeth*, the District Court disagreed with the PTO's interpretation that the entire period during which an application is pending before the PTO (excluding the periods of 35 U.S.C. § 154(b)(1)(B)(i)-(iii)) is the relevant period for determining whether periods of delay under 35 U.S.C. § 154(b)(1)(B) (37 C.F.R. §§ 1.702(b) and 1.703(b)) overlap with periods of delay under 35 U.S.C. § 154(b)(1)(A) (37 C.F.R. §§ 1.702(a) and 1.703(a)). Specifically, the District Court disagreed with the PTO's interpretation because it considers an application as delayed under 35 U.S.C. § 154(b)(1)(B) during the period before it has been delayed under the three-year pendency provision. *See, e.g., Wyeth* at pages 8-9. In addition, the District Court found the language in 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) regarding the overlap of the periods was not ambiguous and

indicated that delays under 35 U.S.C. § 154(b)(1)(B) ("B delays" in *Wyeth*) begin "when the PTO has failed to issue a patent within three years, not before." *Wyeth* at page 9.

ARGUMENT

Patentees do not disagree with the Office's calculation of PTA under 35 U.S.C. § 154(b)(1)(A) (557 days) or the Office's calculation of PTA reduction under 37 C.F.R. § 1.704 (240 days), which gave rise to the August 7, 2008 Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that indicated a PTA of 317 days. The Patentees also do not disagree with the Office's calculation of an additional 46 days of PTA for failing to issue the patent within four months of paying the issue fee, resulting in a delay of 603 days (557 + 46 days) under 35 U.S.C. § 154(b)(1)(A). However, Patentees disagree with the Office's only crediting an additional 248 days (instead of 805 days) of PTA for the failure to issue the patent within 3 years of filing pursuant to 35 U.S.C. § 154(b)(1)(B), presumably based on an implicit finding that the 851 days of delay under 35 U.S.C. § 154(b)(1)(B) overlap with the entire 603 day delay under 35 U.S.C. § 154(b)(1)(A) (rather than only overlapping with 46 days of delay under 35 U.S.C. § 154(b)(1)(A)).

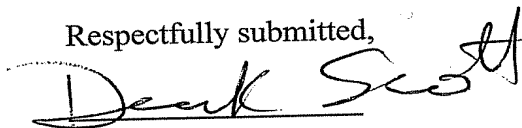
In view of the *Wyeth* decision, it is clear that delays under 35 U.S.C. § 154(b)(1)(B) (and therefore under 37 C.F.R. §§ 1.702(b) and 1.703(b)) do not begin until the PTO has failed to issue a patent within three years, subject to the exclusions of 35 U.S.C. § 154(b)(1)(B)(i)-(iii). In the instant case, the period of 557 days of adjustment under 37 C.F.R. § 1.703(a), ending with the July, 7, 2006 mailing of the restriction requirement, clearly does not overlap with the period of adjustment under 37 C.F.R. § 1.703(b), beginning on October 28, 2006. Accordingly, Patentees are entitled to the period of adjustment for both 603 days of delay (557 + 46 days) under 37 C.F.R. § 1.703(a) and 805 days of delay (851 days minus 46 days of overlap) under 37 C.F.R. § 1.703(b), rather than the larger period under 37 C.F.R. § 1.703(b) as currently calculated. As such, Patentees are entitled to an additional 557 days of PTA for the period of delay under 37 C.F.R. § 1.703(b), such that the total correct PTA for U.S. Patent No. 7,419,662 is 1168.

Accordingly, Patentees respectfully request that the PTA for the instant application be reconsidered and corrected in light of the facts and arguments above. If any further information is required, please contact the undersigned at the number listed below. Please

charge any additional fees due in connection with the filing of this paper, or credit any overpayment, to Deposit Account No. 08-3425.

Dated: April 17, 2009

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Derek Scott", written over a horizontal line.

Derek Scott

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HUMAN GENOME SCIENCES, INC.
Intellectual Property Dept.
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Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :
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 Plaintiffs, :
 :
 v. : Civil Action No. 07-1492 (JR)
 :
 JON W. DUDAS, Under Secretary of :
 Commerce for Intellectual :
 Property and Director of U.S. :
 Patent and Trademark Office, :
 :
 Defendant. :

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C.

§ 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b) (1) (A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b) (1) (A) (i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b) (1) (B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b) (1) (b) (i)-(iii), as are periods attributable to the applicant's own delay. See 35 U.S.C. § 154(b) (2) (C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C.

§ 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, *et al.*,
Plaintiffs,
v.
JON W. DUDAS, Under Secretary of
Commerce for Intellectual
Property and Director of U.S.
Patent and Trademark Office,
Defendant.

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: Civil Action No. 07-1492 (JR)
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ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge